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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,135	09/08/2003	Harold M. Aznoian	D0188.70209US01	5402

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EXAMINER	
KASZTEJNA, MATTHEW JOHN	
ART UNIT	PAPER NUMBER
3739	
MAIL DATE	DELIVERY MODE
08/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,135	AZNOIAN ET AL.	
	Examiner	Art Unit	
	MATTHEW J. KASZTEJNA	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-9,12-21,24 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-9,12-21,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/13/8, 5/9/8*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 23, 2008 has been entered.

Notice of Amendment

In response to the amendment filed on June 23, 2008, amended claims 2-9 and 12-21; canceled claims 10-11 and 22-23 and new claims 24-25 and 12 are acknowledged. The rejections of claims 3 and 15 under 35 U.S.C. 112, second paragraph are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-4, 6, 12-18 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,947,983 to Solar et al.

In regards to claims 2, Solar et al. disclose an endoscope and comprising: an endoscope shaft having: proximal and distal ends; one or more uninterrupted lumens extending therethrough (see Figs. 1a-b and 3 and Col. 5, Lines 10-22); a non-detachable treatment accessory integrated at the distal end of the shaft, wherein the treatment accessory comprises a tissue apposition device comprising at least one suction port 111, 121, 131 and at least one needle 140 movable through the accessory to penetrate tissue 211 aspirated into the suction port (see Figs. 2a-e); non-detachable housing 110 for the accessory integrated into the endoscope shaft; one or more accessory control elements 150 extending through the length of the endoscope; an accessory control mechanism mounted at the proximal end of the endoscope (see Col. 3, Line 50 – Col. 4, Line 42). **In regard to method claim 12**, Solar et al. further disclose a method of using the apparatus in combination with an endoscope (see Col. 5, Lines 10-22). Solar et al. disclose a method wherein tissue is sucked into a suction port via vacuum wherein a needle is advanced through the accessory to penetrate the tissue (see Figs. 2a-e and Col. 4, Lines 1-15).

In regards to claims 3, 13, 15, Solar et al. disclose an endoscope, wherein the tissue apposition device 100 includes a cylindrical cartridge that is integrated over a reduced diameter portion of the endoscope shaft (see Fig. 2a). The reduced diameter portion of the shaft can clearly be seen in Figures 2a-e. Furthermore, Solar et al. disclose that the cutting device may be introduced into a body lumen by being placed over the exterior surface of an endoscope (Col. 5, lines 12-23).

In regards to claims 4 and 16, Solar et al. disclose an endoscope wherein the suction port 111, 121, 131 is provided on a side of the cylindrical cartridge (see Figs. 1a-b and 2a and Col. 3, Lines 36-41).

In regards to claims 6 and 18, Solar et al. disclose an endoscope, wherein tissue apposition device 100 comprises a tissue-suturing device 140 having at least one suction port and vacuum chamber 130 and a semi-circular needle 142 configured to be advanced in a circular path that traverses the vacuum chamber and tissue aspirated therein (see Figs. 1c, 2d and 3 and Col. 4, Lines 1-15).

In regards to claims 14, Solar et al. disclose a method for performing an endoscopic procedure, wherein at least one accessory control element 150 extending through the length of the endoscope; and an accessory control mechanism mounted at the proximal end of the endoscope (see Col. 3, Lines 55-65). The push bar 150 is used for positioning and rotating the needle 140 within the second tube. Thus the push bar is inherently controlled at the proximal end of the endoscope, as it is controlled by the user operating the apparatus. Furthermore, Solar et al. teach that such devices having control mechanism mounted at the proximal end of the apparatus are well known in the art and are disclosed by reference according to U.S. Patents 5,643,304 and 5,527,332, both of which clearly show control element and mechanism. The incorporated references (specifically U.S. Patent 5,643,304) teach of working channels used for irrigation, suction and viewing with a control console 51 used to control the functions of each individuals working channel (see Fig. 1 of U.S. Patent 5,643,304).

In regards to claims 24-25, Solar et al. disclose an endoscope and method for performing an endoscopic procedure, wherein the needle 140 is longitudinally slidably through the accessory 100 (see Col. 3, Lines 55-67), as the needle is mounted on a push bar 150 which is used for rotating the needle within the second tube, thus moving the needle longitudinally through the accessory.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-5, 7-9, 12-17 and 19-21 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO/2001/066018 to Gambale et al. in view of U.S. Patent No. 6,010,515 to Swain et al. U.S. Patent Application Publication No. 2003/0208209 to Gambale et al. is a national stage entry of WO/2001/066018 and will be used for citation purposes in the following rejections.

In regards to claims 2, 9, 12 and 21, Gambale et al. disclose an endoscope and comprising: an endoscope shaft having: proximal and distal ends; one or more uninterrupted lumens 88, 92 extending therethrough; a non-detachable treatment accessory 50 integrated at the distal end of the shaft, wherein the treatment accessory comprises a tissue apposition device comprising at least one suction port 86 and at least one needle 80 movable through the accessory to penetrate tissue 211 aspirated into the suction port (see Fig. 6); housing 74 for the accessory integrated into the

endoscope shaft; one or more accessory control elements extending through the length of the endoscope; an accessory control mechanism mounted at the proximal end of the endoscope (see Figs. 7-8 and paragraph 0103); **In regard to method claim 12**, Gambale et al. further disclose a method wherein tissue is sucked into a suction port via vacuum wherein a needle is advanced through the accessory to penetrate the tissue (see paragraphs 0104-0105). Gambale et al. are silent with respect to the cylindrical housing being non-detachable from the endoscope shaft. Swain et al. (referenced by Gambale et al in paragraph 0097) teach of an analogous apparatus wherein a thread guide device is provided which is adapted to be removably or fixedly mounted on the distal end of an endoscope (see abstract lines 1-3). Swain et al. teach that the device 2 may be *mounted* via in any appropriate fashion as is well known in the art. It would have been obvious to one skilled in the art at the time the invention was made to mount the treatment accessory 50 of Gambale et al. in a non-detachable fashion to ensure that the accessory is securely fixed to the endoscope shaft and prevent detachment of the accessory from the shaft during a surgical procedure within a the body as taught by Swain et al. and is well known in the art.

In regards to claims 3, 13 and 15, Gambale et al. disclose an endoscope, wherein the tissue apposition device 50 includes a cylindrical cartridge 74 that is integrated over a reduced diameter portion of the endoscope shaft (see Figs 4-5).

In regards to claims 4 and 16, Gambale et al. disclose an endoscope wherein the suction port 86 is provided on a side of the cylindrical cartridge (see Fig. 6 and paragraph 0102).

In regards to claims 5 and 17, Gambale et al. disclose an endoscope wherein the suction port further comprises a partition wall that forces aspirated tissue to form into two separate tissue mounds (wall not labeled, see separation between the multiple suction ports 86 in Figure 6). Furthermore, as broadly as claimed, the partition wall may alternatively be interpreted as being the area between air passages 88 through which are is sucked via a vacuum (see paragraph 0103).

In regards to claims 7-8 and 19-20, Gambale et al. disclose an integrated endoscope and medical treatment accessory, wherein the treatment accessory further comprises a tissue apposition device having at least one suction port and vacuum chamber having a bottom surface and an optical viewing port and air and water port are present on the bottom surface (see paragraphs 0011-0012). Gambale et al. teach that working channels used for viewing and air/water are well known in the art and thus incorporates by reference U.S. Pat. Nos. 5,792,153 and 5,080,663. The endoscope is provided with a viewing channel, which is not shown, but which terminates at a lens on the distal face of the endoscope. Thus, Gambale et al. meets the limitations as broadly as claimed of the recited claims as U.S. Pat. Nos. 5,792,153 and 5,080,663 incorporated by reference teach of the claims working channel as being well known in the art. **In regard to claims 9 and 21,** Gambale et al. disclose an endoscope wherein the tissue apposition device 50 includes an angulated distal face that is oriented at an acute angle from the longitudinal axis of the endoscope and wherein the suction port 88, 90 is open on the distal face of the vacuum chamber having a back wall surface and

also wherein the needle is configured to be advanced so that it traverses the vacuum chamber at a parallel orientation (see Figs. 7-8 and paragraphs 0104-0106).

In regards to claim 14, Gambale et al. disclose a method for performing an endoscopic procedure, wherein at least one accessory control element (control valves not shown) extending through the length of the endoscope; and an accessory control mechanism mounted at the proximal end of the endoscope (see paragraph 0103). Furthermore, Gambale et al. disclose that the needle 80 is longitudinally slideable via pusher 98 (see paragraph 0105).

In regards to claims 24-25, Gambale et al. disclose an endoscope and method for performing an endoscopic procedure, wherein the needle 140 is longitudinally slidably through the accessory 100 (see paragraph 0105, line 1).

Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,947,983 to Solar et al. in view of U.S. Patent No. 6,626,930 to Allen et al.

In regards to claims 5 and 17, Solar et al. disclose an endoscope and comprising: an endoscope shaft having: proximal and distal ends; one or more uninterrupted lumens extending therethrough (see Figs. 1a-b and 3); a non-detachable treatment accessory integrated at the distal end of the shaft, wherein the treatment accessory further comprises a tissue apposition device comprising at least one suction port 11, 121, 131 and at least one needle 140 longitudinally slidable through the accessory to penetrate tissue 211 aspirated into the suction port (see Figs. 2a-e); non-detachable housing 110 for the accessory integrated into the endoscope shaft; one or

more accessory control elements extending through the length of the endoscope; an accessory control mechanism mounted at the proximal end of the endoscope (see Col. 3, Line 50 – Col. 4, Line 42). Solar et al. are silent with respect to wherein the suction port further comprises a partition wall that forces aspirated tissue to form into two separate tissue mounds. Allen et al. teach of an analogous apparatus having a pair of distally-directed tissue separating walls 44 extending therefrom, and defining a gap 46 therebetween (see Figs. 3a-e). It would have been obvious to one skilled in the art at the time the invention was made to include a tissue diving wall in the apparatus of Solar et al. to have greater control over the tissue entering the vacuum ports as taught by Allen et al.

Response to Arguments

Applicant's arguments filed June 23, 2008 have been fully considered but they are not persuasive.

Applicant states that the apparatus of Solar et al. is not designed for visually examining the interior of a body cavity or hollow organ. Examiner disagrees. Solar et al. disclose that the tubes 110, 120 and 130 are introduced into the body by any suitable means. It is preferred, however, that the device of the present invention be inserted into the body in association with an endoscope (e.g., within a working channel of an endoscope or over the exterior surface of an endoscope), which allows for the in-situ identification of diseased tissue. Once the endoscope is positioned to a target location within a body lumen, the device 100 is extended from the endoscope working channel to grasp, cut and remove diseased tissue (see Col. 5, Lines 12-23). Thus if the cutting

device 100 is place over the exterior of an endoscope, as taught by Solar et al., then the treatment accessory 10 would be *integrated* with the endoscope and the two elements would share the same shaft as the instrument is inserted within the body. Further evidence of the integrated device is shown taught by Solar et al. by the incorporated references U.S. Patents 5,643,304 and 5,527,332, both of which clearly show the treatment accessories being integrated into the endoscope shafts. Thus, as broadly as claimed, Solar et al. meets the limitations of the recited claims.

Applicant's arguments with respect to the rejections of claims 2-3, 7-9, 12-15 and 19-21 under Gambale et al. have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./
Examiner, Art Unit 3739

7/24/8